

## **REMARKS**

### **Claim Status**

Claim 1 has been amended to specify the concentration of the triglyceride to be from about 0.25 to about 10% for the feed composition. The support for this concentration range is found on page 6, lines 14-15 of the instant specification as well as in original claim 13. Claim 1 has further been amended to recite that said industrially prepared triglyceride consists essentially of C<sub>6</sub>-C<sub>10</sub> medium chain fatty acid triglyceride. Support for this amendment is found in Table 1, on page 10 and in Table 10, on page 22 of the instant specification, which demonstrate that most of the industrially prepared triglycerides comprise substantially C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids. For example, industrially prepared MCTG 1 contains 99.6% of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids, and MCTG 2 contains 100% of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids. *See* Table 1, page 10 of the instant specification.

Claims 9-12 have been amended to refer to proper antecedent basis.

Claims 22-25 have been cancelled.

Claim 26 has been added. Support for this new claim is found on page 3, lines 26-30 of the instant specification.

Pursuant to 37 C.F.R. §1.118(a), Applicants respectfully submit that the above amendments do not introduce any new material into the application.

With the present amendments, 11 claims are pending in the application, namely, claims 1-3, 9-12, 14, 20-21 and 26.

### **Rejection under 35 U.S.C. § 112, First Paragraph**

Claims 1-3, 8-12, 14 and 20-25 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with written description requirement. In response, Applicants have deleted the range of “about 0.05 to about 20%” from claim 1 and replaced it with the range of “about 0.25 to about 10%”, which was cited in original claim 13. Thus, this rejection is now overcome.

### **Rejection under 35 U.S.C. § 112, Second Paragraph**

Claims 1-3, 8-12, 14 and 20-25 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In response, Applicants have amended claims 1 and 9-12 as well as cancelled claims 8 and 22-25 to address the issues raised by the Examiner.

Regarding the term “ppm” cited in claim 1, Applicants again submit that such term is repeatedly used in the specification to refer to the concentration of the enzyme(s) and that one of ordinary skill in the art would know what the term means and how to measure the concentration of the enzyme(s) in ppm.

While Applicants acknowledge that activity units are often used for a measurement of enzyme concentration, it is not the only measurement. Parts per million (“ppm”) is routinely used by one of ordinary skill in the art for a measurement of enzyme concentration. For example, U.S. Pat. Nos. 5,968,792 and 6,620,605 use “ppm” when describing and claiming concentrations of its respective enzymes, of which Applicants point out that the same Examiner was the primary Examiner on U.S. Pat. No. 5,968,792. Another example is Tang *et al.* cited by the Examiner in the instant case, which describes that human milk contains about 0.1 mg BAL

/ml (i.e., about 100 ppm as stated by the Examiner) of human skim milk. In view of these examples, Applicants respectfully request that the Examiner reconsider her rejection on the use of “ppm”.

It is believed that the claims as presently amended are now definite and that the rejection under 35 U.S.C. § 112, second paragraph is now overcome.

### **Rejections under 35 U.S.C. § 102**

Claims 1-3, 8-11 and 20-25 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by breast milk from humans and other animals as evidenced by Tang *et al.* and Hurley. Applicants respectfully traverse this rejection.

The Examiner asserts that breast milk of humans and other lactating animals is the same as the composition as claimed. Applicants disagree.

Claim 1 as presently amended refers to a feed composition comprising about 0.25 to about 10% industrially prepared triglyceride and about 100 to about 10,000 ppm active lipolytic enzyme, wherein the industrially prepared triglyceride consists essentially of C<sub>6</sub>-C<sub>10</sub> medium chain fatty acids.

As discussed previously, the feed composition prepared industrially as claimed in the present invention allows the use of specific concentrations and ratios of different medium chain fatty acids, especially C<sub>6</sub>-C<sub>10</sub> medium chain fatty acids. Unlike naturally occurring triglycerides, industrially prepared triglycerides contain certain medium chain fatty acids in certain concentrations and ratios as desired to produce compositions with better therapeutic effects. *See*

Table 1, page 10 of the instant specification. For example, industrially prepared triglycerides MCTG 1 and MCTG 2 contain much higher concentrations of C<sub>8</sub> and C<sub>10</sub> fatty acids compared to naturally occurring triglycerides, such as butterfat and coconut oil. Particularly, industrially prepared MCTG 1 contains 69.1% of C<sub>8</sub> fatty acids and 27.7% of C<sub>10</sub> fatty acids, and overall 99.6% of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids. MCTG 2 contains 57.5% of C<sub>8</sub> fatty acids and 42.3% of C<sub>10</sub> fatty acids, and overall 100% of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids. In direct contrast, naturally occurring triglyceride butterfat only contains 1.2% of C<sub>8</sub> and 2.6% of C<sub>10</sub> fatty acids, and overall 5.9% of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids. Coconut oil contains only 8.5% of C<sub>8</sub> fatty acids and 6.2% of C<sub>10</sub> fatty acids, and overall 15.4% of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids. Applicants assert that industrially prepared triglycerides comprising about 99.6%-100% of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids are clearly chemically distinguishable from naturally occurring triglycerides comprising about 5.9%-15.4% of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids.

Such “high” content of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids is clearly delineated in claim 1 as presently amended, which uses the language of “consists essentially of”. This “closed ended” claim language excludes other elements from having any essential significance to the combination, that is, it allows some “reading on” additional unspecified substances, i.e., those which do not materially affect the basic and novel characteristics of the claimed invention. See *Special Metals Corp. v. Teledyne Indus., Inc.*, 219 U.S.P.Q. (BNA) 953 (4<sup>th</sup> Cir. 1983) and MPEP 2111.03.

Tang *et al.* and Hurley cited by the Examiner as evidence of the usual composition of human breast milk do not teach each and every element of the presently amended claims. Particularly, human breast milk, which contains naturally occurring triglycerides, does not consist essentially of C<sub>6</sub>-C<sub>10</sub> medium chain fatty acids. Thus, this rejection should be traversed.

### **Rejection under 35 U.S.C. § 103**

Claims 1-3, 8-12, 14 and 20-25 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hull *et al.* taken with Haas *et al.* and Tang *et al.* Applicants respectfully traverse this rejection.

Applicants first draw the Examiner's attention that claim 1 has been amended to recite a feed composition comprising about 0.25 to about 10% industrially prepared triglyceride and about 100 to about 10,000 ppm active lipolytic enzyme, wherein the industrially prepared triglyceride consists essentially of C<sub>6</sub>-C<sub>10</sub> medium chain fatty acids.

As already discussed above, the "high" content of C<sub>6</sub> to C<sub>10</sub> medium chain fatty acids is clearly delineated in claim 1 as presently amended, which uses the language of "consists essentially of". There is a clear correlation between the claimed composition as presently amended and the extensive unexpected results touted. Although only industrially prepared MCTG 1 was selected for the experiments presented in Example 2, the results obtained from using MCTG 1 is believed to be extendable to those presently claimed feed compositions containing industrially prepared triglyceride which consists essentially of C<sub>6</sub>-C<sub>10</sub> medium chain fatty acids. MCTG 1 feeds, which comprise 5% MCTG 1 and are supplemented with 1000 ppm of lipase L2 or L5, serve as representative examples of the feed composition as presently claimed. See page 11, Table 2 of the instant specification. The scope of the showing is indeed commensurate with the scope of claims as presently amended.

Applicants believe that the high content of C<sub>6</sub>-C<sub>10</sub> medium chain fatty acids in the industrially prepared triglycerides as well as the combined effect of such triglycerides and the

lipolytic enzyme lead to the unexpected therapeutic effects of the feed composition as presently claimed. As described in the instant specification (*see* Example 2, Tables 3 and 4, pages 12-13), industrially prepared MCTG 1 demonstrates a 100 to 1000-fold activity in reducing bacterial count when compared to compositions of naturally occurring triglycerides such as coconut oil or butterfat combined with the lipase(s), which only show a 10-fold activity.

In the instant invention, the gradual lipolysis of the triglycerides by the lipolytic enzyme results in the release of essentially C<sub>6</sub>-C<sub>10</sub> medium chain fatty acids in the stomach, providing a physiological environment in the stomach of early-weaned animals that regulates and stabilizes gastrointestinal flora. The presently claimed composition has unexpectedly high bacteriostatic and bactericidal activity against Gram-positive and Gram negative bacteria. *See* Experiment 4, Table 9 of the instant specification.

Hull *et al.* discloses a method of producing sweet cream buttermilk from lipolyzed cream. Hull's products contain a desired balance of fatty acids having chain lengths in the range of C<sub>4</sub> to C<sub>10</sub> but consisting predominantly of butyric acid. *See* Col. 2, lines 22-29. One of ordinary skill in the art would know that butyric acid, having a structure formula of CH<sub>3</sub>CH<sub>2</sub>CH<sub>2</sub>CO<sub>2</sub>H, is a C<sub>4</sub> fatty acid. Clearly, Hull *et al.* does not teach or suggest a composition containing industrially prepared triglycerides consisting essentially of C<sub>6</sub>-C<sub>10</sub> medium chain fatty acids.

Haas *et al.* discloses a composition comprising fat and protein, which has been conditioned by emulsifying the fat and treating the mixture with lipase and protease. *See* Abstract. During the treatment, the fat reacts with the lipase to produce free fatty acids and mono- and diglycerides (emphasis added). *See* Col. 2, lines 17-19. Clearly, Haas *et al.* does not

teach or suggest a composition containing industrially prepared triglycerides consisting essentially of C<sub>6</sub>-C<sub>10</sub> medium chain fatty acids (emphasis added).

Tang *et al.* discloses a dietary composition comprising a fat-containing nutritional base fortified with bile salt-activated lipase. See claim 1 and Abstract. The nutritional base disclosed in Tang *et al.* contains naturally occurring triglycerides, which differ greatly from the industrially prepared triglycerides as discussed above.

In view of the above remarks, neither the feed composition presently claimed, nor the above-mentioned unexpected benefits provided by such compositions, would have been apparent from Hull *et al.*, Haas *et al.*, and Tang *et al.* Hull, alone or combined. Therefore, Hull *et al.* taken with Haas *et al.* and Tang *et al.* would not have rendered obvious the present invention as claimed. Applicants respectfully request that the rejection under 35 U.S.C. 103 be traversed.

This document is filed timely. No fee is believed to be due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is authorized to deduct said fees from Deposit Account No. 01-2508/13475.0003.PCUS00.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Wendy Davis".

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Date: October 20, 2005